

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE DEPOMED PATENT
LITIGATION**

Civil Action No.: 2:13-cv-04507 (CCC-MF)

OPINION

CECCHI, District Judge.

I. INTRODUCTION

This matter comes before the Court upon application of Plaintiffs Depomed, Inc. (“Depomed”) and Grünenthal Pharmaceuticals, Inc. (“Grünenthal”) (collectively, “Plaintiffs”) as well as Defendants Actavis Elizabeth LLC (“Actavis”), Alkem Laboratories Limited (“Alkem”), and Roxane Laboratories, Inc. (“Roxane”) (collectively, “Defendants”) for claim construction, pursuant to Local Patent Rule 4.5. The parties submitted their Joint Claim Construction and Prehearing Statement (“JCCPS”) on July 11, 2014, and the request was fully briefed on September 26, 2014. The parties presented their arguments at a *Markman* hearing on November 25, 2014.¹ Having considered the parties’ written submissions and oral arguments, the Court sets forth its construction of the disputed terms below.

II. BACKGROUND

A. Procedural Background

This is a consolidated patent infringement action brought by Plaintiffs in connection with each Defendant’s filing of an Abbreviated New Drug Application (“ANDA”) under the Hatch-Waxman Act. Plaintiffs in this patent infringement litigation assert four patents in six consolidated

¹ Subsequent to the *Markman* hearing, the parties met and conferred and agreed to reduce the number of terms for the Court to construe.

cases (Case Nos. 13-4507, 13-6929, 13-7803, 14-3941, 14-4617, and 15-6797). The four asserted patents are U.S. Reissue Patent 39,593 (the “RE593 Patent”), U.S. Patent 7,994,364 (the “‘364 Patent”), United States Patent 8,536,130 (the “‘130 Patent”), and United States Patent 8,309,060 (the “‘060 Patent”).²

Currently before the Court is the parties’ dispute over the construction of four patent claim terms—three terms in the RE593 patent and one term in the ‘364 patent. Both the RE593 patent and the ‘364 patent are being asserted against all defendants.

The four claim terms for the Court to construe are:

- “an isolated . . . diastereo[iso]mer”
- “such that X and the dimethylamino group are disposed threo in relation to each other”
- “(–)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride(–21)”
- “essentially the same as”

B. Scientific Background

The specific claim construction issues in this case involve complex principles of organic chemistry. Specifically, this case involves stereochemistry, which is the branch of chemistry concerned with the three-dimensional arrangement of compounds and the effect it has on chemical reactions. The following is a brief recitation of some of the chemistry principles relevant to the construction of the disputed claim terms.

² On August 24, 2015, the Honorable Thomas P. Griesa of the Southern District of New York entered judgment invalidating the relevant claims of the ‘060 Patent in *Endo Pharmaceuticals, Inc. et al. v. Amneal Pharmaceuticals, LLC et al.*, Civil Action Nos. 12-cv-8115, -8060, -8317, 13-cv-435, -436 (S.D.N.Y.). Subsequent to that judgment, this Court entered an order staying all proceedings relating to the ‘060 Patent pending appeal of Judge Griesa’s decision. (ECF No. 287.) Therefore, at this time, the Court will not construe any disputed terms in the ‘060 patent.

“Molecules that have the same chemical substituents, but different spatial arrangements, are referred to as stereoisomers.” *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1372 (Fed. Cir. 2006). Importantly, stereoisomers of a drug substance can have different biological effects. See Declaration of William R. Roush, Ph.D. (“Roush Decl.”) ¶ 35(e), ECF No. 141-21.

Stereoisomers may have different physical properties, such as solubility, melting point, chromatographic mobility, and rotation of plain polarized light. See Roush Decl. ¶ 35(e). Stereoisomers that rotate polarized light to the right are referred to as (+) or “d”; stereoisomers that rotate polarized light to the left are referred to as (-) or “l.” *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 348 F. Supp. 2d 713, 720-21 (N.D. W. Va. 2004); *Sanofi-Synthelabo*, 470 F.3d at 1372; Roush Decl. ¶ 37.

There are two types of stereoisomers: (1) enantiomers and (2) diastereomers. “Enantiomers are a pair of stereoisomers that are non-superimposable mirror images of each other.” *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1286 (Fed. Cir. 2006). This characteristic is “often likened to the relative structures of a person’s right and left hands.” *Ortho-McNeil*, 348 F. Supp. 2d at 720. A molecule may have a maximum of one enantiomer—there is only one other molecule that can be its mirror image. Enantiomers have the same melting points as each other and they rotate plain polarized light in equal but opposite directions.

“Diastereomers,” in contrast, are stereoisomers that are not mirror images of each other. Roush Decl. ¶ 35(e); see also JCCPS at 3. Diastereomers have different physical properties such as solubility, melting point temperature, chromatographic mobility, etcetera. See Roush Decl. ¶ 35(e).

The number of diastereomers (and, by extension, the number of stereoisomers) that a molecule has is determined by the number of chiral centers in the molecule. A chiral center is a

carbon atom that is bonded to four different substituent groups. “Chemists also distinguish between enantiomers and diastereomers by designating an enantiomer as either ‘R’ or ‘S’ based upon the arrangement of certain atoms at the enantiomer’s ‘chiral center.’ Where one enantiomer is an ‘R,’ the other will be an ‘S.’” *Ortho-McNeil*, 348 F. Supp. 2d at 720-21.

In the study of stereochemistry, it is often necessary to depict three-dimensional molecules in two dimensions. There are a number of ways that chemists achieve this. One such way is by using “Fischer projections.” A Fischer projection is a drawing that depicts a three-dimensional molecule in a two-dimensional plane. Pls. Opening Br. at 7; Roxane Opening Br. at 21. In a Fischer projection, thin solid horizontal and vertical lines are used to indicate whether a three-dimensional chemical group attached to one of those lines projects into or out of the plane of the page. Pls. Opening Br. at 7. For example, the groups at the top and bottom of the vertical line in a Fischer projection are understood to project behind the plane of the paper, while groups to the left and right of the vertical line are understood to project in front of the plane of the paper. *Id.*; Roush Decl. ¶ 41.

III. LEGAL STANDARD

Claim construction is a matter of law for the Court to decide. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). “It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1319 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

The Court begins a claim construction analysis by examining the intrinsic evidence, which includes the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). If the claim term remains unclear or

ambiguous after examining the intrinsic evidence, the Court may turn to extrinsic evidence, *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216 (Fed. Cir. 1995), which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995).

“A claim construction analysis must begin and remain centered on the claim language itself.” *Innova*, 381 F.3d at 1116. “[I]t is that language that the patentee chose to use to particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.” *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (internal quotation marks omitted). The claims themselves and the context in which a term is used within the claims can “provide substantial guidance as to the meaning of particular claim terms.” *Phillips*, 415 F.3d at 1314. In addition, other claims of the patent may be useful in construing a claim term, as “claim terms are normally used consistently throughout the patent.” *Id.* Similarly, claims that differ from each other may provide insight into how a term should be read. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991).

“The claims, of course, do not stand alone. Rather, they are part of a fully integrated written instrument” called the “specification.” *Phillips*, 415 F.3d at 1315. The Federal Circuit has said that “claims must be read in view of the specification.” *Markman*, 52 F.3d at 978. For this reason, “the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics*, 90 F.3d at 1582. Therefore, after examining the claims, “it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning.” *Vitronics*, 90 F.3d at 1582. “For claim construction purposes, the description may act

as a sort of dictionary, which explains the invention and may define terms used in the claims.” *Markman*, 52 F.3d at 979.

Finally, the Court should also examine the prosecution history. *Phillips*, 415 F.3d at 1317. The prosecution history is the complete record of the proceedings before the United States Patent and Trademark Office (“USPTO”), and “can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id*; see also *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013) (noting that the district court was correct in relying on prosecution statements when the specification contained no reference to the disputed term).

There is a heavy presumption that a claim term conveys its ordinary and customary meaning, which “is the meaning that the term would have to a person of ordinary skill in the art³ in question at the time of the invention.” *Phillips*, 415 F.3d at 1313. But a patentee may overcome this presumption and choose “to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term.” *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999); see also *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1353 (Fed. Cir. 2000); *Markman*, 52 F.3d at 979-80.

“[I]deally there should be no ‘ambiguity’ in claim language to one of ordinary skill in the art that would require resort to evidence outside the specification and prosecution history.” *Markman*, 52 F.3d at 986. However, if there remains ambiguity, the Court may consult extrinsic evidence. Extrinsic evidence is generally “less significant than the intrinsic record in determining

³ In this Opinion, the Court will refer to a person of ordinary skill in the art as a “POSA.” This term includes all iterations of this concept, such as “a person having ordinary skill in the art,” “one of ordinary skill in the art,” etcetera.

the legally operative meaning of disputed claim language.” *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (quotations omitted). In addition, extrinsic evidence ordinarily should not contradict intrinsic evidence. *Phillips*, 415 F.3d at 1322-23. Therefore, extrinsic evidence must be viewed within the context of intrinsic evidence. *Id.* at 1319.

Consistent with the law of claim construction as discussed above, this Court will first look to the language of the disputed claim term itself in the context of the claim in which it appears as well as the other claims in the patent. The Court will then look to the patent specification and read the claim in view of the specification. Next, the Court will look to the prosecution history to determine whether and how the patentee understood the invention. Finally, to the extent necessary, the Court will look to the extrinsic evidence (such as expert declarations) to resolve any remaining ambiguities. The Court will view the expert declarations within the context of the intrinsic evidence.

IV. DISCUSSION – RE593 PATENT

On June 19, 2001, the USPTO issued United States Patent No. 6,248,737, entitled “1-Phenyl-3-Dimethylaminopropane Compounds With A Pharmacological Effect,” which was reissued as the RE593 Patent on April 24, 2007.

The RE593 Patent claims certain 1-phenyl-3-dimethylaminopropane compounds, which can allegedly treat chronic and non-chronic pain without causing the adverse side effects traditionally associated with opioid treatments. *See, e.g.*, RE593 Patent at 1:35-57. The RE593 patent also claims a method of preparing these compounds and the use of these compounds as pharmaceutical active ingredients. *See generally* RE593 Patent.

The Court must construe three terms in the RE593 Patent: (1) “an isolated . . . diastereo[iso]mer”; (2) “such that X and the dimethylamino group are disposed threo in relation to

each other”; and (3) “(-)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride(-21).” The Court addresses each term for construction in turn.

A. “[A]n isolated . . . diastereo[iso]mer”

This claim term appears in asserted claims 9, 25-26, 28, 30, 33-34, 36, 40-42, 44, 46, 49-50, 52, 56, 126-129, 141, and 143-145 of the RE593 Patent. Claim 9 is representative of the use of this term in all of these asserted claims. Claim 9 states:

An isolated 1-phenyl-3-dimethylaminopropane diastereoisomer having a configuration corresponding to at least one of formulae Ia’ and Ic’ ... wherein X represents [listing possible variations] ... or a salt thereof with a physiologically acceptable acid. [].

RE593 Patent at 25:35-26:18 (emphasis added). The parties’ proposed constructions for this claim term are as follows:

| <u>Plaintiffs’ Proposed Construction</u> | <u>Actavis’s Proposed Construction</u> | <u>Alkem’s Proposed Construction</u> | <u>Roxane’s Proposed Construction</u> |
|---|--|---|--|
| Plain Meaning “An isolated . . . diastereo[iso]mer means “a diastereo[iso]mer that may have present small amounts of other diastereo[iso]mers of the same compound, such as would be remaining after separation or synthesis.” | “a diastereomer having a diastereomeric purity of no less than that achieved by preparative chiral chromatography or equivalent separation methods, including a diastereomeric purity of approximately 97% or greater” | Indefinite term or, in the alternative, “without allowing detectable amounts of another stereoisomer” | “a diastereoisomer separated from other compounds” |

There is no dispute concerning the meaning of the word “diastereomer”—the parties agree that diastereomers are stereoisomers which are not mirror images of each other. The parties also

agree that “diastereomer” has the same meaning as “diastereoisomer.”⁴ The disagreement therefore centers on the meaning of “isolated” in the context of the claim term.

i. The Court Adopts Plaintiffs’ Construction

There appear to be two disputes between the parties concerning the word “isolated”:

- “Isolated” relative to what other compounds?
- How pure must the compound be in order for it to be considered “isolated?”

For the following reasons, the Court finds that: (1) the claimed molecule must only be “isolated” from its diastereomers, not from its enantiomer; and (2) the isolated compound may have small amounts of its diastereomers, such as would be remaining after separation or synthesis. The Court will, therefore, adopt Plaintiffs’ proposed construction and construes “an isolated . . . diastereo[iso]mer” as:

a diastereo[iso]mer that may have present small amounts of other diastereo[iso]mers of the same compound, such as would be remaining after separation or synthesis.

1. The compound must be isolated relative to its diastereomers.

Beginning with the plain language of the claim term, it states “isolated . . . diastereoisomer.” RE593 Patent at claim 9. It does not state “isolated . . . enantiomer,” “isolated . . . stereoisomer,” “isolated . . . molecule,” or “isolated . . . compound.” The Court reads this to be a clear intention of the patentee to claim a diastereomer that has been isolated only from its diastereomers.

The remainder of the claim language provides further evidence that “isolated” is relative to diastereomers. Claims 9, 25, and 34 contain the following language:

“An isolated 1-phenyl-3-dimethylaminopropane diastereoisomer having a configuration corresponding to *at least one of* formulae Ia’

⁴ For simplicity, the Court will use the term “diastereomer” throughout this Opinion, unless quoting a specific source.

and Ic’.”

Formula Ia’ and formula Ic’ are enantiomers of each other. *See* Roush Decl. ¶ 81. By reciting that the configuration corresponds to “at least one of” the two enantiomers, the claim expressly includes a mixture of the two enantiomers.⁵ In other words, the claimed compound need not be isolated from its enantiomer. Therefore, the isolation is required only from the diastereomers.

2. *The isolated compound may have small amounts of its diastereomers, such as would be remaining after separation or synthesis.*

The claim language does not provide guidance regarding the level of isolation that is required. A plain reading of the specification, however, demonstrates that the claimed compound is of substantial purity, but need not be absolutely pure. In other words, the claimed compound need not be completely devoid of the undesired diastereomer, detected or undetected.

The specification does not explicitly use the term “isolated” in the context of diastereomers. It does, however, discuss separating enantiomers from each other. The Court, therefore, construes the isolation of diastereomers from the context provided by enantiomers. The specification has numerous examples where the melting point and/or optical rotation of two separated enantiomers differ.⁶ *See* RE593 Patent at 6:1-32, 12:1-7, 12:1-46, 17:10-50, 19:1-67. A POSA would understand these differences to occur because of the presence of other compounds in addition to the isolated compound. *See* Roush Decl. ¶ 66. Thus, the patent suggests that small amounts of other substances may be present and detectable after a separation.

⁵ The parties have not raised the term “at least one of” as a term for construction by the Court. This claim term has received inconsistent treatment by the Federal Circuit. *Compare Enzo Biochem, Inc. v. Applera Corp.*, 780 F.3d 1149, 1156 (Fed. Cir. 2015), with *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337 (Fed. Cir. 2008). Absent any argument to the contrary, the Court understands its plain meaning in this context to mean “one or both” of the two drawn structures.

⁶ To illustrate, Examples 22 and 23 report melting point temperature ranges for enantiomers of 174-176 and 170-172, respectively. RE593 Patent at 17:10-50.

Moreover, in light of the practical limitations of science, district courts (including this Court) have been reluctant to adopt constructions that require 100 percent purity. *See Teva Neuroscience, Inc. v. Watson Labs., Inc.*, No. 2:10-cv-05078, 2013 U.S. Dist. LEXIS 54871, at *17 (D.N.J. Apr. 12, 2013); *see also Ortho-McNeil, Inc., et al. v. Johnson & Johnson Pharma. Res. & Dev., LLC, et al.*, 348 F. Supp. 2d 713, 730 (N.D. W. Va. 2004) (“[A]lthough one of ordinary skill in the art would have understood the claim to the compound . . . to be substantially pure . . . the realities of science would have led such a skilled artisan to conclude that purity was not 100 percent.”). The same rationale applies to this claim term—100 percent isolation is not required.

ii. The Court Does Not Adopt Defendants’ Proposed Constructions

Defendants’ individually proposed constructions for this term vary greatly:

- Roxane’s construction, “a diastereoisomer separated from other compounds,” does not allow for the presence of any other compounds (including impurities) except for the claimed molecule. It also requires the isolation to be 100 percent complete.
- Alkem argues that the claim term is indefinite. Alternatively, Alkem’s construction, “without allowing detectable amounts of another stereoisomer,” requires isolation of the claimed molecule from all of its stereoisomers—including its enantiomer. It also requires that the isolation be complete enough that the amount of remaining stereoisomers is so small as to be beyond detection.
- Actavis’ construction, “a diastereomer having a diastereomeric purity of no less than that achieved by preparative chiral chromatography or equivalent separation methods, including a diastereomeric purity of approximately 97% or greater,” is closest to Plaintiffs’ construction. Actavis agrees that isolation is relative to diastereomers and need not be 100 percent or beyond detection of remaining diastereomers. However, Actavis’s construction includes purity limitations based on a percentage (97 percent) and separation methods (chiral chromatography).

For the following reasons, the Court does not adopt Defendants’ proposed constructions.

1. *Isolation is not relative to “other compounds” (Roxane) or “another stereoisomer” (Alkem).*

Based on the claim language, if Roxane’s or Alkem’s construction were correct, the word “diastereomer” in the claim term is superfluous. Under Roxane’s construction, if the claim were intended to isolate the claimed compound from all other compounds, it would have said “isolated . . . compound.” Similarly, under Alkem’s construction, if the claim were intended to isolate one stereoisomer, it would have said “isolated . . . stereoisomer.” But because the claim says “isolated . . . diastereomer,” the Court construes the term “isolated” to be relative to the diastereomers. Furthermore, because Alkem’s construction would require isolation from all stereoisomers—including the enantiomer—it would exclude the expressly claimed mixture of Formula Ia’ and Ic’.

Roxane also points to the specification and the prosecution history. Regarding the specification, Roxane argues that “isolated . . . diastereomer” claims in the patent refer to only the isolated molecule while the “analgesic composition” claims can be mixed with other compounds. *See* Roxane Opening Br. at 10-11. However, the patent abstract states that it relates to “1-phenyl-3-dimethylaminopropane compounds . . . *and the use of these substances as analgesic active ingredients in pharmaceutical compositions.*” RE593 Patent at Abstract; *see also id.* at 1:15-18. The Court reads “these substances” as referring to the “isolated . . . diastereomers,” which are clearly intended to be used as pharmaceutical active ingredients in analgesic compounds. It would be counterintuitive to read the patent such that the “isolated . . . diastereomer” of the invention ceases to be an “isolated . . . diastereomer” once it is used for its intended purpose.

Regarding the prosecution history, Roxane points out that the patentees first amended the claims to include the term “isolated” in response to a rejection of the application as obvious over German Patent DE 1,051,281 to Hans Henecka (“Henecka”). Roxane Opening Br. at 12. Henecka merely discloses the configuration of the atoms in the claimed molecule in two dimensions, with

no disclosure of stereochemistry. *See* Henecka at 1:22-46. The patentees amended the claims to include the word “isolated” and argued that “[t]he claimed isolated diastereoisomers exhibit distinct properties from the racemic⁷ compounds.” ECF No. 82-14 at 5. This history indicates that the patentees intended the term “isolated” to indicate the importance of the stereochemistry. It does not convey the intent to indicate isolation from other compounds (such as manufacturing impurities or carriers and fillers used to create a dosage form).

2. The claim term is not indefinite (Alkem).

Alkem argues the term “isolated” is indefinite under 35 U.S.C. § 112 in light of *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2123 (2014). *See* Alkem Opening Br. at 8-9. In *Nautilus*, the Supreme Court held that a claim is definite when “viewed in light of the specification and prosecution history, [it] informs those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 134 S. Ct. at 2129. This newly articulated definiteness standard “mandates clarity, while recognizing that absolute precision is unattainable.” *Id.*

In support of its indefiniteness argument, Alkem relies on the absence of a “specific purity limitation” in the RE593 Patent specification. Alkem Resp. Br. at 3. However, the Federal Circuit has held that terms of degree are definite where the specification provided enough certainty to a POSA when read in the context of the invention. *See, e.g., Enzo Biochem, Inc. v. Applera Corp.*,

⁷ The patentees distinguished their “isolated” diastereomer from the “racemic” compounds of Henecka. The term “racemic” (or “racemate”) refers to a mixture “consist[ing] of identical amounts of (+) and (-) enantiomer.” RE593 Patent at 1:50-51. Neither the intrinsic nor extrinsic evidence provides any indication that a racemic mixture contains diastereomers of the enantiomers in the mixture. As discussed above, the claim language expressly allows for a mixture of the two enantiomers of a compound. To the extent that there is an issue under 35 U.S.C. § 251 of the patentees recapturing subject matter that they surrendered during prosecution, that is an issue of validity rather than claim construction and the Court will not consider it at this time. *See Generation II Orthotics, Inc. v. Med. Tech., Inc.*, 263 F.3d 1356, 1365 (Fed. Cir. 2001) (allowing claims to be construed to preserve their validity only “where the proposed claim construction . . . does not revise or ignore the explicit language of the claims”).

599 F.3d 1325, 1335 (Fed. Cir. 2010) (holding that “not interfering substantially” was definite despite being defined in the specification “without reference to a precise numerical measurement”). Here, although the patent specification does not discuss isolating a diastereomer, the examples of isolated enantiomers provide the necessary context for a POSA to understand with “reasonable certainty” the level of isolation that the patentees intended in claiming an “isolated” diastereomer. *See, e.g.*, RE593 Patent, Examples 24 and 25 (purified enantiomers with remaining impurities).

3. *The claimed compound need not be absolutely (Roxane) or detectably (Alkem) pure.*

Both Roxane and Alkem argue the term “isolated” conveys a strict purity limitation—Roxane argues absolute purity is required and Alkem argues detectable purity is required. The Court finds the intrinsic and extrinsic evidence do not support such strict limitations. A plain reading of the specification leads to the conclusion that the claimed compound must be of substantial purity, but not necessarily completely devoid of even a single undesired diastereomer, detected or undetected.

Alkem argues that its construction comports with the plain language of the claims because the patentees could have used “substantially pure” or another similar phrase. However, especially in light of the Supreme Court’s recognition that “absolute precision [in claim drafting] is unattainable,” *Nautilus*, 134 S. Ct. at 2123, this Court is not persuaded by this argument.

Roxane and Alkem also rely on the prosecution history. Roxane points to the patentee’s amendment of the claims to recite an “isolated . . . diastereomer,” allegedly narrowing the claims to distinguish them from the prior art’s mixture of stereoisomers. Roxane Opening Br. at 12. However, Plaintiffs do not presently seek to broaden the disputed claims to encompass, for example, mixtures of diastereomers, which would clearly be outside of the scope of the claim.

Instead, Plaintiffs' construction defines the required diastereomer purity level while allowing for impurities and other substances common to typical manufacturing, synthesis, and separation processes.

Alkem points to an inventor declaration in the prosecution history in which Examples 24 and 25 were referred to as "pure" threo enantiomers. Alkem Opening Br. at 12, Ex. 4 at ¶ 8. However, nothing in the prosecution history indicates the patentee defined "pure" or otherwise intended that word to limit the scope of the word "isolated" to substances without detectable amounts of other compounds.

4. A threshold purity percentage and specific separation method (Actavis) are not warranted.

Actavis's construction is "a diastereomer having a diastereomeric purity of *no less than that achieved by preparative chiral chromatography* or equivalent separation methods, including a diastereomeric *purity of approximately 97% or greater.*" JCCPS (emphasis added). Actavis cites a contemporary textbook, which states that a compound having 97 percent diastereomeric purity is "diasteromerically pure." Actavis Opening Br. at 33; Alexi Decl. Ex. N. However, while extrinsic evidence can be useful in limited circumstances, here a threshold purity percentage is not supported by the intrinsic record. The specification provides numerous examples of the purification processes by which a compound in a mixture becomes isolated from other compounds. A POSA would understand that an isolated compound is significantly more pure than a mixture, but nowhere does the specification recite or imply a threshold purity percentage.

Actavis also argues that examples in the specification reciting chiral chromatography should be read as limitations on the scope of the claims. *See, e.g.*, RE593 Patent at 6:24-25 ("Racemate separation was effected on a Chirocel OD column."). However, the Federal Circuit has held it is improper to "import limitations into claims from examples or embodiments appearing

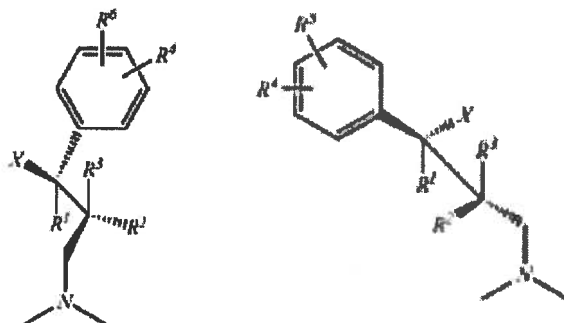
only in a patent's written description, even when a specification describes very specific embodiments of the invention" *JVW Enters. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1335 (Fed. Cir. 2005). Plaintiffs also offer expert testimony that chiral chromatography is not a method used for separating diastereomers, but rather is a method used for separating enantiomers. *See* Pls. Resp. Br. at 3 (citing deposition testimony from Dr. Roush). In addition, the specification contains references to other purification methods, such as crystallization and column chromatography. Therefore, this claim term is not limited to only chiral preparative chromatography.

For the foregoing reasons, the Court does not adopt Defendants' proposed constructions of the term "an isolated . . . diastereo[iso]mer." The Court adopts Plaintiffs' construction and construes the term to mean "a diastereo[iso]mer that may have present small amounts of other diastereo[iso]mers of the same compound, such as would be remaining after separation or synthesis."

B. "[S]uch that X and the dimethylamino group are disposed threo in relation to each other"

This claim term appears in asserted claims 25-26, 28, 30, 33, 41-42, 44, 46, 49, 66-67, 69, 71, 74, 76, 95-96, 98, 100, 103, 105, 126, 128, 130, 132, and 137 of the RE593 Patent. Claim 25 is representative of the use of this term in all of the relevant claims. Claim 25 states:

An isolated 1-phenyl-3-dimethylaminopropane diastereoisomer having a configuration corresponding to at least one of the formulae Ia' and Ic':



wherein

... such that X and the dimethylamino group are disposed threo in relation to each other, . . .

RE593 Patent at 27:51-28:22 (emphasis added). The parties' proposed constructions for this claim term are as follows:

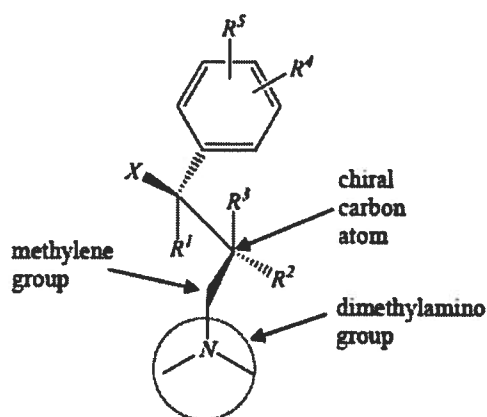
| <u>Plaintiffs' Proposed Construction</u> | <u>Actavis's Proposed Construction</u> | <u>Alkem's Proposed Construction</u> | <u>Roxane's Proposed Construction</u> |
|---|--|--------------------------------------|---------------------------------------|
| <p>Plain Meaning</p> <p>"[S]uch that X and the dimethylamino group are disposed threo in relation to each other" means "the substituent X in formulae Ia' and/or Ic' and the substituent containing a dimethylamino group in formulae Ia' and/or Ic' are disposed threo in relation to each other."</p> | <p>"such that X and N(CH₃)₂ are bound to two adjacent chiral centers and are on the same side in the Fischer projection"</p> | | |

The parties disagree primarily on the meaning of two terms present in the disputed phrase:

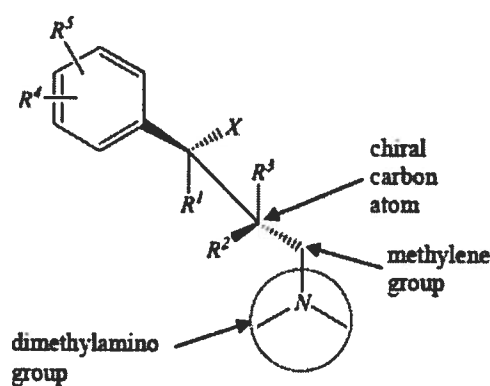
(i) "dimethylamino group"; and (ii) "threo." Although these terms appear in the same disputed claim term, they present completely separate issues. Therefore, the Court will address "dimethylamino group" and "threo" separately.

i. "Dimethylamino Group"

For clarity, the Court relies (as the parties did) on the conventional molecular drawings taken from Claim 25 of the RE593 Patent, reproduced below with relevant annotations added:



Structural Formula Ia'



Structural Formula Ic'

Pls. Opening Br. at 20, Roxane Resp. Br. at 13. The focus of this dispute is on the “methylene group” appearing between the circled “dimethylamino group” and the “chiral carbon atom.” The parties agree that the term “dimethylamino group” refers to a chemical group on a carbon chain that contains a nitrogen atom attached to two methyl substituents, denoted by “[N(CH₃)₂].” They disagree on whether the dimethylamino group in the claimed molecule must be directly attached to a chiral carbon or whether it can be attached to a different carbon in the carbon chain that is not a chiral carbon.

Defendants argue that the dimethylamino group must be directly attached to a chiral carbon. Plaintiffs argue that the dimethylamino group does not have to be directly attached to the chiral carbon; rather it can be attached to a non-chiral carbon in the carbon chain, such that there is a carbon (*i.e.*, a methylene group) between the chiral carbon and the dimethylamino group. For the reasons set forth below, the Court agrees with Plaintiffs.

1. The Court Adopts Plaintiffs' Construction

Plaintiffs' construction is correct because it is consistent with the drawn molecule structures in the claim itself as well as every disclosed compound (drawn or named) in the patent. Plaintiffs' construction includes the phrase “*the substituent containing* a dimethylamino group,”

meaning the dimethylamino group does not have to be directly attached to the chiral carbon but can instead be attached to a carbon that is attached to the chiral carbon. In the drawn structures of the claim itself, the dimethylamino group is *not directly attached* to a chiral carbon, but rather it is attached to a carbon atom that is attached to the chiral carbon. The same is true of every compound depicted or named in the patent. Accordingly, Plaintiffs' construction, including the words "the substituent containing a dimethylamino group," is correct.

2. Defendants' Proposed Construction is Incorrect

Defendants' proposed construction would require the "dimethylamino group" to be directly attached to the chiral carbon atom. But Defendants' construction is wrong because it would exclude from its scope—and flat-out contradict—the exact structure depicted in the claims, as well as every other named and drawn compound in the entire patent. *See Young v. Lumenis*, 492 F.3d 1336, 1346 (Fed. Cir. 2007) (noting that a drawing in the specification supported the appropriate construction).

Defendants support their proposed construction based on general propositions about stereochemistry, which focuses on groups attached to chiral carbons. Accordingly, Defendants suggest, because the claim term uses a stereochemistry term ("disposed threo"), it must mean the dimethylamino group is one of the groups attached to a chiral carbon. However, Defendants' argument fails to consider *this* molecule in the context of the claims and specification.

Defendants also argue that if the dimethylamino group were attached to another carbon attached to the chiral carbon, then the claim would have called it a "dimethylaminomethylene group" rather than a "dimethylamino group." But this argument fails because it would require the molecule to have four carbons (three for the propane chain, plus one for the methylene group) where there are actually only three shown in the depicted molecule. Therefore, Defendants'

argument is incorrect. The Court adopts Plaintiffs' construction and construes the "dimethylamino group" portion of this term as "the substituent containing the dimethylamino group."

ii. "Threo"

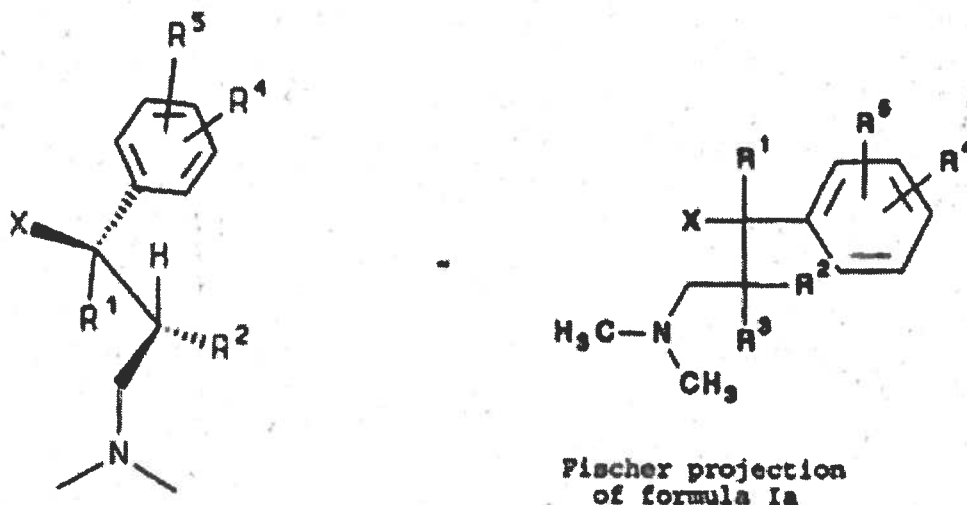
Having determined what the term "dimethylamino group" means, the Court now addresses the second dispute within this claim term—the construction of "threo." The parties agree the term "threo" is used to describe the location of groups on a Fischer projection. The dispute is over which Fischer projection to examine and which groups to look at.

There is only one Fischer projection in the entire intrinsic evidence, and it appears in the prosecution history. The Court, therefore, finds that the one Fischer projection provided is the appropriate Fischer projection to examine. *See Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013) (noting that the district court was correct in relying on prosecution statements when the specification contained no reference to the disputed term).

That one Fischer projection appears in the argument made by the patentees to the PTO on November 24, 1997 (the "November 24th Amendment"), in which the patentees acted as their own lexicographer by explicitly defining the term "threo" for use in this patent.⁸ *See* Case No. 13-6929, ECF No. 82-7. The patentees stated:

In the context of the present invention, the "threo" configuration refers to compounds which in the corresponding "Fischer projection" of formula Ia have the substituent "X" and the dimethylaminomethylene group arranged on the same side as illustrated by the following formulas.

⁸ Because the patentees provided an explicit definition for "threo" with one Fischer projection, the Court makes no comment on Plaintiffs' argument for a plain meaning of the term "threo" obtained by examining the "most similar" groups on the "preferred" Fischer projection.



Case No. 13-6929, ECF No. 82-7.

However, the patentees clearly made a mistake in the Fischer projection provided. Simply put, the two structures drawn in the November 24th Amendment are intended to portray the same molecule—but they do not. The structure on the left is the correct drawing of formula Ia that appears throughout the patent and at least nine separate times in the claims. *See, e.g.*, RE593 Patent at 2:52-65, claims 6, 9, 10, 25, 34, 66, 77, 95, 106. The structure on the right is clearly intended to be a Fischer projection of the same⁹ formula Ia, but it contains a typographical mistake. The R² and R³ groups have been inadvertently switched, which means that it is actually the Fischer projection for a different unclaimed molecule.

Based on the tutorials provided by the parties, *see, e.g.*, Roush Decl. at ¶¶ 41-45, the Court can easily identify and correct the mistake. The top of the Fischer projection is correct.¹⁰ But the

⁹ Though the diagram says “formula Ia,” it is actually intended to be formula Ia’ because the molecule has the unsubstituted R³ group rather than the substituted H group of formula Ia. This distinction is of no consequence.

¹⁰ When R¹ projects behind the plane of the paper on top, X projects forward on the left, and the carbon ring projects forward on the right.

bottom of the Fischer projection contains a mistake.¹¹ A POSA would have immediately recognized this mistake. And a POSA would have recognized that when R² and R³ are switched and placed in their correct locations, the Fischer projection accurately portrays the claimed molecule.¹²

Tellingly, Defendants do not dispute that there is a mistake in the Fischer projection. However, by focusing on the “public notice” function of lexicography, they urge the Court to hold Plaintiffs to the exact (mistaken) definition provided in the prosecution history. *See* Roxane Opening Br. at 23; Roxane Resp. Br. at 17-19. In the instance of a purported statement made in error during prosecution, the relevant inquiry for the court construing the claims is whether a reading of the remainder of the intrinsic record as a whole would lead a POSA to the conclusion that a mistake was made. *See, e.g., Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1348 (Fed. Cir. 2001) (“An error in the prosecution record must be viewed as . . . would it have been apparent to the interested reader that an error was made, such that it would be unfair to enforce the error.”). Generally, if a POSA who reads the intrinsic record knows the statement to be incorrect, the patentee should not be bound to it during claim construction. *Id.* In this case, a POSA reading the November 24th Amendment in the context of the patent would have immediately known exactly what the mistake was, how to correct it, and how the patentees intended to define the term. This is precisely the type of mistake to which the patentees should not be bound.

¹¹ When R³ projects behind the plane of the paper on the bottom, R² *should* project forward on the *left* and the substituent containing the dimethylamino group *should* project forward on the *right*. However, this is the opposite of the configuration shown in the November 24th Amendment.

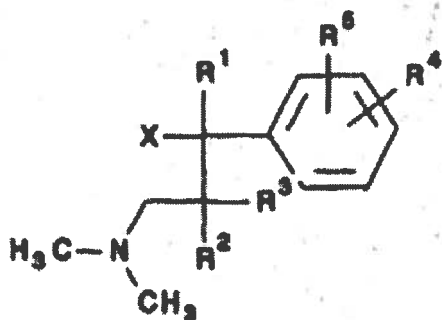
¹² When R² projects behind the plane of the paper on the bottom, R³ projects forward on the right and the substituent containing the dimethylamino group projects forward on the left.

The Court will, therefore, correct the mistake such that the Fischer projection can be properly examined. The Court will use the definition of “threo” explicitly provided by the patentees.

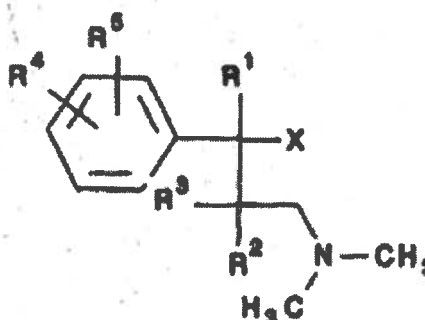
iii. The Court’s Construction

For the reasons set forth above, the Court construes “such that X and the dimethylamino group are disposed threo in relation to each other” as:

such that X and the substituent containing the dimethylamino group are bound to two adjacent chiral centers and are on the same side in the following correct Fischer projections for formulae Ia’ and Ic’:



Fischer projection for formula Ia'



Fischer projection for formula Ic'

C. “(–)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride (-21)”

This claim term is found in asserted claims 61 and 117 of the RE593 Patent. Claim 61 is representative of both instances. Claim 61 recites:

(–)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride (–21).

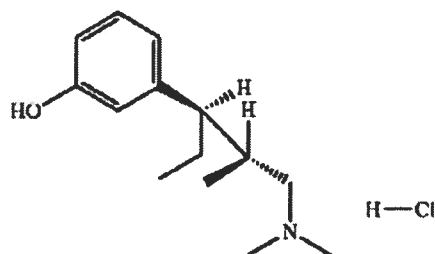
RE593 Patent at 32:19-21. The parties’ proposed constructions are:

| <u>Plaintiffs' Proposed Construction</u> | <u>Actavis's Proposed Construction</u> | <u>Alkem's Proposed Construction</u> | <u>Roxane's Proposed Construction</u> |
|--|---|--------------------------------------|---------------------------------------|
| <p>Plain Meaning</p> <p>"(-)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride (-21)" refers to "the chemical compound (-)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride depicted by the structural formula identified by the number (-21) in Example 25 of the RE593 patent."</p> | <p>"the compound of Example 25 having a melting point of 168-170° C and a specific rotation of $[\alpha]_D^{RT} = -27.5^\circ$ (c=0.97; methanol)"</p> | | |

The dispute is over the effect and meaning of the parenthetical "(-21)" at the end of the chemical formula in the claim. The parties agree that "(-21)" performs at least two functions: First, the "-" indicates that the substance is a single enantiomer that rotates plane-polarized light in a particular direction (a "+" would indicate the enantiomer rotates light in the opposite direction). Second, "21" is a sequential number used to identify, at the very least, one of the chemical structures depicted in the RE593 Patent. RE593 Patent at 19:12-30 (defining the chemical structure in Example 25 as "-21"). Thus, there is no dispute that "(-21)" refers to a single enantiomer structure seen in Example 25 that rotates light in the "-" direction.

However, while Example 25 and the surrounding text in the specification provide a conventional chemical drawing (including the same chemical formula recited in claims 61 and 117), Example 25 also provides data pertaining to the substance's melting point and specific polarization angle. *Id.* The relevant portion of the specification is reproduced below:

Example 25



(-)-(1R, [2S], 2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride (-21)

Enantiomer (-21) was obtained in 45% yield under the conditions cited in Example 24 from (-1), which was prepared as in Example 2.

m.p.: 168–170° C.

$[\alpha]_D^{25} = -27.5^\circ$ (c=0.97; methanol)

Id. Defendants argue that the “(-21)” incorporates the melting point and polarization data from the specification. Plaintiffs argue that such data was neither claimed nor incorporated by reference. For the reasons below, the Court agrees with Plaintiffs.

i. The Court Adopts Plaintiffs’ Construction

Plaintiffs’ construction is consistent with the way the specification is written. In each instance of a reference numeral in the specification, the reference numeral is introduced immediately after the chemical name. *See, e.g.*, RE593 Patent at 7:25-26, 16:45-46, 19:24-25. The reference numeral is introduced before any description of the synthesis or physical characteristics of the compound. Once the chemical name and reference numeral have been introduced, the specification goes on to use the reference numeral as a short-hand notation for the name of the compound when it describes the reaction, the yield, the melting point, and the optical rotation. *See, e.g.*, RE593 Patent at 19:26-30. Therefore, the Court will adopt Plaintiffs’ construction and construe the term “(-)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride (-21)” as:

“the chemical compound (-)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride depicted by the structural

formula identified by the number (–21) in Example 25 of the RE593 patent.”

ii. The Court Does Not Adopt Defendants’ Construction

Defendants primarily argue three reasons why the melting point and optical rotation values should be imported as limitations on the claims. First, Defendants argue that failing to import these limitations into the claim term would render “(–21)” superfluous. However, “(–21)” is not superfluous because “(–21)” clearly designates Example 25 in the specification as the claimed compound, and thereby provides a clear mechanism for a POSA to locate the claimed compound in the specification text. This function is captured in Plaintiffs’ proposed construction because it expressly construes the claim term “. . . depicted . . . in Example 25 of the RE593 Patent.”¹³

Second, Defendants argue, a POSA would require the melting point and optical rotation limitations to “know whether a compound that has purportedly been synthesized is in fact the compound that was intended to be synthesized.” Roxane Resp. at 26. However, absent further evidence to the contrary, the Court is hesitant to impart absolute values, such as the ones proposed by Defendants, into the claim limitations. *See Edwards Sys. Tech., Inc. v. Digital Control Sys., Inc.*, 99 F. App’x 911, 916 (Fed. Cir. 2004) (holding that references to a “0.1 micron” size limitation in the specification should not be construed as limitations on the claims). Neither the claims nor the specification indicate the patentees intended to limit the claim to these strict quantitative measurements without allowance for the variances in manufacturing, including differing levels of impurities.

¹³ Plaintiffs also cite the *Manual of Patent Examining Procedure* and two district court cases purportedly indicating that reference numerals should be given no weight in construing the scope of claims. *See* Pls. Opening Br. at 29-30. The parties disagree on whether these sources are factually relevant to the present case and how much authority they should be afforded. However, construing this term does not require addressing this question because, as explained above, the Court’s construction does give meaning to all the claim terms, including “(–21).”

And third, Defendants argue that the patentees' statement that the "specific compound claims . . . are specifically exemplified" in the prosecution history means "that the scope of these claims is confined to the *specific* compound of Example 25 – and *only* that product – as identified by its . . . melting point and optical rotation" Roxane Opening Br. at 24. However, the context makes clear that the patentees were not limiting the scope of the claims but rather they were explaining to the examiner that the amendment did not add new matter to the patent. *See* 35 U.S.C. § 251 (forbidding "new matter"). Additionally, the phrase "specifically exemplified" is a grammatical variation of the phrase "specific example." Thus, the patentees' statement in the prosecution history simply refers to a specific example known in the RE593 Patent as Example 25. It does not impart a further meaning to "(–21)." Thus the Court adopts Plaintiffs' construction.

V. DISCUSSION – '364 PATENT

On August 9, 2011, the USPTO issued the '364 Patent, entitled "Crystalline Forms of (–)-(1R,2R)-3-(3-Dimethylamino-1-Ethyl-2-Methylpropyl)-Phenol Hydrochloride." In contrast to the RE593 Patent (which claims a number of different 1-Phenyl-3-Dimethylaminopropane compounds), the '364 Patent is limited to one such compound: (–)-(1R,2R)-3-(3-Dimethylamino-1-Ethyl-2-Methylpropyl)-Phenol Hydrochloride. More specifically, the '364 claims a particular crystalline form of that compound.

The '364 Patent specification describes the depiction of the claimed crystalline form of the compound by two-dimensional graphs obtained through a measurement technique known as "X-Ray Powder Diffraction" ("XRPD") analysis.¹⁴ The specification provides several XRPD plots to

¹⁴ To perform the measurement in an XRPD test, a focused X-ray beam is shot at a sample at a specific angle of incidence. *See* Pls. Opening Br. at 31. The X-rays scatter or "diffract" in a unique way depending on the crystalline structure of the sample. *Id.* The locations (angles or "2-theta values") and intensities of the diffracted X-rays are then measured and plotted. *Id.* Every compound has a unique diffraction pattern, analogous to a fingerprint, and the diffraction pattern

which the claims explicitly refer. The specification also discloses that XRPD is an appropriate technique for distinguishing the claimed invention from other compounds. ‘364 Patent at 2:20-36.

The Court must construe one claim term in the ‘364 patent: “essentially the same as.”

A. “[E]ssentially the same as”

This claim term appears in Claim 3 of the ‘364 Patent. Claim 3 states:

The crystalline Form A of (–)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride according to claim 1 exhibiting an X-ray pattern (2-theta values) in a powder diffraction when measured using Cu K_α radiation *essentially the same as* that provided in FIG. 1.

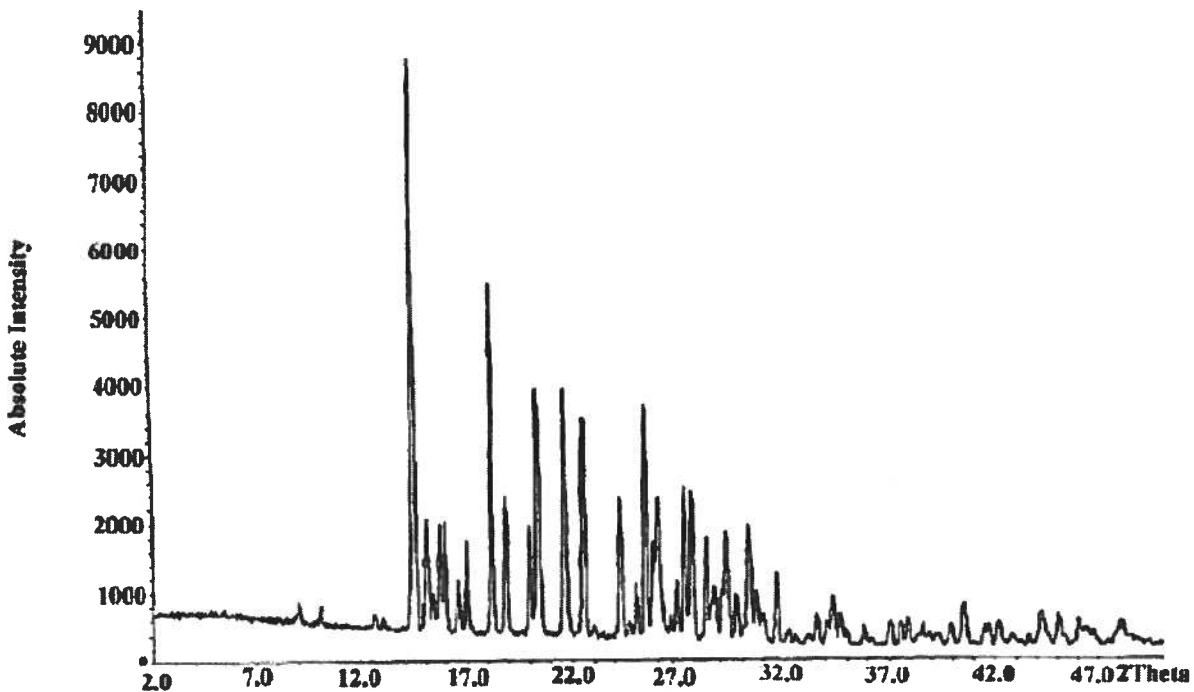
‘364 Patent at 19:11-15 (emphasis added). The parties’ proposed constructions for this term are as follows:

| <u>Plaintiffs’ Proposed Construction</u> | <u>Actavis’s Proposed Construction</u> | <u>Alkem’s Proposed Construction</u> | <u>Roxane’s Proposed Construction</u> |
|--|---|--|--|
| Plain Meaning “X-ray pattern (2-theta values) in a powder diffraction pattern when measured using CuK _α radiation essentially the same as that provided in FIG. 1” means an “X-ray pattern (2-theta values) in a powder diffraction pattern when measured using CuK _α radiation essentially the same as that provided in FIG. 1.” | No construction necessary—plain meaning | “having essentially the same peak locations and intensities” | No construction necessary—plain meaning |

The claim references and incorporates Figure 1 of the ‘364 Patent, which shows the pattern resulting from an XRPD analysis. See ‘364 Patent, Fig. 1. The parties agree on the basic mechanics of an XRPD test. The disputed claim language refers to a particular X-ray powder

of an unknown sample can be compared to other samples or standard reference patterns of known compounds.

diffraction pattern which is reproduced in Figure 1 of the '364 Patent specification and shown below:



'364 Patent, Fig. 1. Plaintiffs, Actavis, and Roxane all propose that no construction is necessary. Alkem alone argues that not construing this term will inevitably lead to an “I know it when I see it” battle of experts over whether two XRPD patterns are essentially the same. Alkem Opening Br. at 15-19. For the reasons set forth below, the Court disagrees with Alkem.

i. The Court Adopts Plaintiffs, Actavis, and Roxane’s Construction

Plaintiffs acknowledge that “both location and intensity [of the peaks] are important, and are part of what must be considered in determining whether two XRPD patterns are essentially the same.” Pls. Resp. Br. at 24. Where the parties disagree is whether two XRPD patterns can be essentially the same even if the peak locations differ to some measurable extent. Alkem argues that two XRPD patterns are “essentially the same” only if there are mere “insubstantial

differences.” However, the specification provides clear and unmistakable language that the patentees did not intend to limit Claim 3 further:

The most important X-ray lines (2-theta values) in terms of intensity characterizing Form A of (–)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride showing one or a combination of the following in a powder diffraction measurement when measured using Cu K α radiation at ambient temperature are 14.5 \pm 0.2, 18.2 \pm 0.2, 20.4 \pm 0.2, 21.7 \pm 0.2 and 25.5 \pm 0.2.

‘364 Patent at 2:20-26. Here, the patentee clearly disclosed that the location of the peak intensities will have a margin of error, in this case “ \pm 0.2.”

In addition, Plaintiffs argue that knowing whether two XRPD patterns are “essentially the same” requires more than simply analyzing the peak locations and intensities. Figure 1 provides not only the location and intensity of the peaks but also the breadth of those peaks, which is a consideration in comparing XRPD patterns. Pls. Resp. at 34; *see* Declaration of Joel Bernstein (“Bernstein Decl.”) ¶¶ 38-42, ECF No. 141-24. The Court therefore agrees that limiting “essentially the same as” to only peak intensities and locations without allowing for either variance in the peak locations or additional factors such as peak breadth is contrary to the claim language and specification.

ii. The Court Does Not Adopt Alkem’s Construction

Alkem makes three arguments in support of its proposed construction. First, Alkem argues that the intrinsic record supports a construction that includes both peak locations and intensities. Alkem relies on the data listed in Table 1 of the ‘364 Patent to support its argument that “peak locations and intensities” are proper limitations for this claim. However, the patentees expressly chose to claim the “pattern” in Figure 1 in Claim 3 and not the “data” in Table 1. *See Interactive Gift Express*, 256 F.3d at 1331 (“[I]t is that language that the patentee chose to use to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’”).

Alkem also relies on a statement in the specification regarding “look[ing] at . . . the lines with sufficient intensity at 2-theta values” Alkem Opening Br. at 17; ‘364 Patent at 2:27-32. That statement, however, refers to a comparison of the diffraction patterns of Form A and Form B, two patterns that happen to be distinguishable from each other based only on peak intensities and locations. But that narrow example cannot limit the scope of the claimed pattern, which inherently includes all of the characteristics of the pattern.

Alkem’s second argument is based on the doctrine of claim differentiation, which requires a dependent claim to be narrower than its independent claim. *See Dow Chem. Co. v. United States*, 226 F.3d 1334, 1341-42 (Fed. Cir. 2000). Alkem argues that “if [dependent] claim 3 is construed in such a way as to remove the peak intensity consideration, even as a measure of relative intensity, then it would add nothing to [independent] claim 1,” and thus it would not be narrower. Alkem Resp. at 11. Alkem’s premise is that giving the term “essentially the same as” its plain meaning in the context of comparing XRPD patterns, as all other parties propose, would not allow consideration of peak intensity. That premise is incorrect because the plain meaning allows for consideration of all relevant characteristics of the XRPD patterns, including peak intensity and others (such as peak breadth).

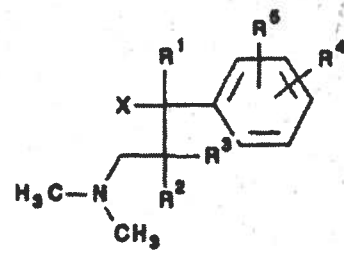
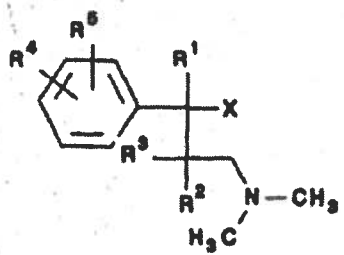
Third, Alkem argues that the plain and ordinary meaning of Claim 3 is indefinite. Alkem raises a concern that not construing this term will provide a lack of guidance for the experts at trial. However, Alkem offers only attorney argument that a POSA would not understand the scope of the claim in light of the specification. The specification, itself, provides guidance as to how much the location of the peak intensities may vary (± 0.2) when comparing XRPD plots. ‘364 Patent at 2:20-26. A POSA would understand how to apply the guidance of the specification in evaluating whether two XRPD plots were “essentially the same.” Plaintiffs also offer expert testimony that

interpreting XRPD plots is a task a POSA would know how to perform. Pls. Resp. Br. at 26-27; Bernstein Deposition at 93:3-12. Thus, the Court finds that the plain meaning of Claim 3 is not indefinite because, when “viewed in light of the specification and prosecution history, [it] informs those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 134 S. Ct. at 2129.

In light of the foregoing, the Court agrees with Plaintiffs, Actavis, and Roxane that the term “essentially the same as” has its plain meaning which requires no construction.

VI. CONCLUSION

The Court construes the disputed claim terms of the RE593 Patent as follows:

| <u>Disputed Claim Term</u> | <u>Court's Construction</u> |
|--|--|
| an isolated . . . diastereo[iso]mer | a disastereo[iso]mer that may have present small amounts of other diastereo[iso]mers of the same compound, such as would be remaining after separation or synthesis |
| such that X and the dimethylamino group are disposed threo in relation to each other | <p>such that X and the substituent containing the dimethylamino group are bound to two adjacent chiral centers and are on the same side in the following correct Fischer projections for formulae Ia' and Ic':</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Fischer projection for formula Ia'</p> </div> <div style="text-align: center;">  <p>Fischer projection for formula Ic'</p> </div> </div> |
| (-)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride (-21) | the chemical compound (-)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride depicted by the structural formula identified by the number (-21) in Example 25 of the RE593 patent, |

The Court construes the disputed claim term of the '364 Patent as follows:

| <u>Disputed Claim Term</u> | <u>Court's Construction</u> |
|----------------------------|---|
| essentially the same as | No construction necessary – plain meaning |

An appropriate Order accompanies this Opinion.

Dated: February 5, 2016


HON. CLAIRE C. CECCHI
 United States District Judge